

REMARKS

Applicant would like to thank the Examiner for the teleconference of May 13, 2003 with Applicant's attorney, John Han, during which the claims and cited reference, Oz, was discussed. Claims 1-97 are pending in the present application. Claims 1 and 47 have been amended. Accordingly, claims 1-97 are currently under consideration. Amendment and cancellation of certain claims is not to be construed as a dedication to the public of any subject matter of the claims as previously presented.

**Rejections Under 35 U.S.C. § 102(e)**

The Office has rejected claims 1-3, 5, 7-9, 24-36, 41, 42, and 47-68 as allegedly being anticipated by Oz et al. (U.S. Patent No. 6,269,819 B1).

In support of the rejection of claims 1-3, 5, 7-9, 24-36, 41, 42, and 47-68, the Office Action (Paper No. 12) states the following on pages 2-3:

As to claims 1-3, 5, 7-9, 15, 29, 33, 41, 47-51, 55, 57, 63, and 64, Oz et al. disclose method and apparatus for treating tissue near a cardiac valve to modify flow through the valve, the apparatus comprising: a cinching member having a central region and at least two anchoring regions on opposing ends of the central region, wherein each anchoring region is configured to be anchoring to opposing areas of tissue and urge the areas of tissue towards each other, the cinching member being further configured for delivery through a catheter to the tissue whereby the cinching member has a first shape during the delivery and a second shape after the delivery. See Figure 2 and 30.

As to claims 12-14, and 65, their cinching member is configured to approximate a portion of periphery defined by the valve as presently claimed.

As to claims 24-28 and 60-62, the central region of the cinching member defines a first plane (the plane perpendicular to the center of the cinching member) and the anchoring regions define a second plane. The second plane defines an angle relative to the first plane, wherein the magnitude of the angle relates the force applied to the encircling member. See Fig. 29.

As to claims 16, 17, 42, 53, and 54, their cinching member is a biocompatible material selected from the group consisting of shape memory Titanium alloy (Col. 5, lines 14-17).

As to claims 10, 11, 30-32, 52, 56, 58, and 59, the cinching member is selected from the group consisting of hooks, clips, screws, V-shapes, and U-shapes. See Figures 21-30.

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As to claims 34, 36, 66, and 68, they use a guide wire (stylet) to advance the cinching member (Col. 6, lines 29-34).

Independent claim 1 has been amended to recite "opposing areas of tissue against or adjacent to an annulus of the valve" and claim 47 has been amended to similarly recite "a first area of the tissue against or adjacent to an annulus of the valve" and "a second area of the tissue against or adjacent to the annulus of the valve." (For support, specification, [0134].) On the other hand, Oz shows and describes a device which is used for "grabbing and clasping together the anterior and posterior leaflets of the valve." (Oz, 2: 35-36.) Furthermore, Oz shows and describes its clip as applied only *directly onto the leaflets* of the valve. (Oz, 7: 24-25; Fig. 30.) Oz, therefore, fails to show or describe a device which is used to be anchored to "opposing areas of tissue against or adjacent to an annulus of the valve", as recited in the amended claims. Therefore, Oz cannot anticipate independent claims 1 and 47.

Dependent claims 2, 3, 5, 7-9, 24-36, 41, 42, and 48-68 depend ultimately from claims 1 and 47 and are patentable for at least the same reasons above. Accordingly, Applicant respectfully requests the reconsideration and withdrawal of the rejections under 35 U.S.C. § 102(e).

#### Rejections Under 35 U.S.C. § 103(a)

The Office has rejected claims 18-23, 37-40, 43-46, and 69-75 as allegedly being unpatentable over Oz et al. variously in view of Muller (U.S. Pat. No. 5,725,521) and Crowley et al. (U.S. Pat. No. 6,004,269).

In support of the rejection of claims 37 and 69 over Oz et al. in view of Muller, the Office Action (Paper No. 12) states the following on page 4:

Although Oz et al., described above, use sliding mechanism to advance and retract the guide wire (stylet), they do not particularly teach its type. Muller teaches an alternative heart modifying device and methods comprising a thumb-slide advancing mechanism. Thus, it would have been obvious to one skilled in the art at the time of the applicant's invention to modify the device of Oz et al. with Muller and use a thumb-slide as an alternative mechanism.

In support of the rejection of claims 18-23, 38-40, 43-46, and 70-75 over Oz et al. in view of Crowley, the Office Action (Paper No. 12) states the following on pages 4-5:

Oz et al., described above, do not teach the use of therapeutic coating, radiopaque material selected from the group consisting of platinum, gold, etc., or an ultrasound sensor connected to a monitor for guiding the system as presently claimed.

However, Crowley et al. disclose an ultrasound guided catheter and method for modifying the flow through a cardiac valve, the device comprising: therapeutic agents; radiopaque markers; coating material selected from the group consisting of platinum and gold; and an ultrasound sensor disposed at the tip of the catheter device for monitoring the treatment and operations of the device. Thus, it would have been obvious to one skilled in the art at the time of the applicant's invention to modify Oz et al. with Crowley et al. to employ radiopaque markers and ultrasound sensors in order to monitor the operation of the system. It would have been further obvious to one skilled in the art at the time of applicant's invention to use gold or platinum as a alternative coating material.

Dependent claims 18-23, 37-40, 43-46, and 69-75 depend ultimately from independent claims 1 and 47 and are patentable over Oz for at least the same reasons as above. Therefore, Muller, Crowley, or any other reference, necessarily fails to cure the defects of Oz. Accordingly, Applicant respectfully requests the reconsideration and withdrawal of the rejections under 35 U.S.C. § 103(a).

#### **Allowable Subject Matter**

The Office has indicated that claims 4 and 6 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office Action and to include all of the limitations of the base claim and any intervening claims.

The Office has further indicated that claims 76-97 are allowed.

Applicants acknowledge the allowable subject matter with thanks. However, Applicants contend that in light of the remarks above, all pending claims are allowable and respectfully request allowance therefor.

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**CONCLUSION**

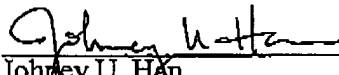
Applicants have, by way of the amendments and remarks presented herein, made a sincere effort to overcome rejections and address all issues that were raised in the outstanding Office Action. Accordingly, reconsideration and allowance of the pending claims are respectfully requested. If it is determined that a telephone conversation would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, Applicant(s) petition(s) for any required relief including extensions of time and authorizes the Assistant Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to Deposit Account No. 03-1952 referencing docket no. 509192000220.

Respectfully submitted,

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